



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,537	09/10/2003	Deborah Ann Evrard	WYNC-0325 (AM101201NP)	4846
38791	7590	11/18/2005	EXAMINER BERNHARDT, EMILY B	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			ART UNIT 1624	PAPER NUMBER
DATE MAILED: 11/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/659,537

Applicant(s)

EVRRARD ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: 6 and 11-48.
Claim(s) rejected: 1-5, 7-10 and 49-52.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☒ Other: See attached response.


Emily Bernhardt
Primary Examiner
Art Unit: 1624

The after final amendment will be entered since it overcomes the rejection under 35 USC 112 based on new matter. However, remaining rejections under par. one remain for the following reasons.

Contrary to what applicants urge both reasoning, evidence (of structure-sensitivity) and case law have been provided to support the enablement rejection. Describing the invention as broadly as it is claimed does not necessarily enable one how to make and use the invention. Literal support for the claims was also present in Surrey previously cited. If Surrey solely required literal support then the earlier Cauvallito decision (127 USPQ 202) would not have been heavily relied on as it was. Note the following quote taken from Cauvallito (regarding literal support at p.205, left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention." With regard to structure-sensitivity (which is evident from the limited data provided in the instant case) note the following quote at p.206, left column: "On the other hand, wide variation in such potency would suggest that it was due in part to the added substituents and might be eliminated or even reversed by many of the possible substituents which had not been tried." The Fisher case cannot be dismissed solely by applicants'

attempt to limit its usefulness to situations where “open-ended recitation” exists. It clearly admonishes that the scope be commensurate with the degree of unpredictability involved in a given case. This has been reiterated in many later decisions involving both closed- and open-ended language. The fact that screening for 5-HT 1A receptor or serotonin reuptake activity may be routine does not necessarily preclude a finding of nonenablement given the lack of test data commensurate in scope with the claims as previously discussed. Note that in *University of Rochester v. G.D.Searle & CO.* 68 USPQ2d 1424 at 1438 the preparation and screening for over 600 compounds was deemed to be undue. Applicants’ scope far exceeds this number. Given the recognized factors that affect receptor binding , namely size (surface area), polarity and electronic effects, the skilled artisan would **not** have sufficient information to predict what type of derivatives from among the many covered by the instant scope would be suitable bioisosteric replacements for the small number of compounds tested. Note MPEP 2164.08(b) which states that claims that read on “... significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative.” Even if such assays are predictive for one or more uses and thus level of skill in the art is high as it applies

to these uses, this does not overcome the deficiencies that exists for remaining Wands factors discussed in previous actions. With regard to the state of the prior art, which is a consideration in the Wands analysis, there is no evidence that compounds of similar structure are known to have such activities.

Note the following quote in MPEP 2106.02: "it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).


With regard to the rejection of claim 49 for scope of uses still present, applicants' newly submitted arguments and reference(s) require more than a cursory review in determining its effectiveness in overcoming the 112 rejection and is thus not in compliance with 37 CFR 1.116(b) and thus will not be considered. See MPEP 714.12- 714.13.

Application/Control Number: 10/659,537
Art Unit: 1624

Page 5

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful; the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Emily Bernhardt
Primary Examiner
Art Unit 1624